AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 16-22 (cancelled)

Claim 23. (currently amended): ~~The composition of claim 16,~~ A composition comprising stable solid particles of a water-insoluble biologically active substance of a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

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a non-aqueous hydrophobic liquid in which said biologically active substance is not soluble or is poorly soluble, and is present in an amount such that the water-insoluble biologically active substance remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition,

wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non aqueous hydrophobic liquid containing particles of surface stabilized water-insoluble biological

substance suspended in the oily droplets of the dispersion and particles of said water-insoluble biologically active substance migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system, and

wherein the biologically active substance is selected from the group consisting of nifedipine, ursodiol, budesonide, paclitaxel, camptothecin, a derivatives of paclitaxel, a derivatives of camptothecin, piroxicam, itraconazole, acyclovir, a derivatives of acyclovir, fenofibrate, cyclosporine, and insulin.

Claim 24. (currently amended): ~~The composition of claim 16~~ A composition comprising stable solid particles of a water-insoluble biologically active substance of a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which is prepared for sustained or controlled delivery of the biologically active substance, having particles dispersed in a non-aqueous carrier system comprised of:

a non-aqueous hydrophobic liquid in which said biologically active substance is not soluble or is poorly soluble, and is present in an amount such that the water-insoluble biologically active substance remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition, wherein upon addition of said composition to a fluid aqueous medium, said composition self-

disperses in said fluid aqueous medium to form a suspension comprising droplets of non aqueous hydrophobic liquid containing particles of surface stabilized waterinsoluble biological substance suspended in the oily droplets of the dispersion and particles of said water-insoluble biologically active substance migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

Claims 25-27 (cancelled)

Claim 28. (currently amended): ~~The composition of claim 16~~ A composition comprising stable solid particles of a water-insoluble biologically active substance of a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

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a non-aqueous hydrophobic liquid in which said biologically active substance is not soluble or is poorly soluble, and is present in an amount such that the water-insoluble biologically active substance remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition, wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non

aqueous hydrophobic liquid containing particles of surface stabilized water-insoluble biological substance suspended in the oily droplets of the dispersion and particles of said water-insoluble biologically active substance migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system, and wherein the composition is contained in a capsule of hard gelatin, or soft gelatin, or starch, which capsule dissolves in a fluid aqueous medium, and which capsule optionally comprises a pharmaceutically acceptable coating for controlling the release of the biologically active substance from said capsule in said fluid aqueous medium.

D1 Claims 29-38 (cancelled)

Claim 39. (previously presented): A composition comprising stable solid particles of itraconazole of a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

a non-aqueous hydrophobic liquid in which itraconazole is not soluble or is poorly soluble, and is present in an amount such that the itraconazole remains insoluble in the non-aqueous hydrophobic liquid;

a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and

a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition,

wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of nonaqueous hydrophobic liquid containing particles of surface stabilized itraconazole suspended in the oily droplets of the dispersion and particles of said itraconazole migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

Claim 40. (previously presented): The composition of claim 39, wherein the non-aqueous hydrophobic liquid is selected such that itraconazole has a solubility of less than 25 mg/mL of the non-aqueous hydrophobic liquid.

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Claim 41. (previously presented): The composition of claim 40, wherein the non-aqueous hydrophobic liquid is selected such that itraconazole has a solubility of from 0.02 to 16.0 mg/mL of the non-aqueous hydrophobic liquid.

Claim 42. (currently amended): The composition of claim 39, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyl oleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, ~~ethyl alcohol,~~ corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, PEG-200, PEG-300, PEG-400, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

Claim 43. (previously presented): The composition of claim 42, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, corn oil PEG6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

Claim 44. (previously presented): The composition of claim 43, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, soybean oil, capric triglyceride, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, apricot kernel oil, linoleic acid, triethyl citrate, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

Claim 45. (currently amended): The composition of claim 39, wherein at least one surfactant component is selected from the group consisting of a natural or synthetic amphiphilic agent; a phospholipid; a nonionic surfactant; a polyoxyethylene fatty alcohol ether; a sorbitan fatty acid ester; a polyoxyethylene sorbitan fatty acid ester; glycerol triacetate; triacetin; a polyethylene glycol; cetyl alcohol; cetostearyl alcohol; stearyl alcohol; a poloxamer; a polaxamine; a polyoxethylene castor oil derivative; vitamin E; D-alpha-tocopheryl polyethylene glycol 1000 succinate; vitamin E TPGS; a PEG glyceryl fatty acid ester; PEG-8 glyceryl caprylate/caprate; PEG-4 glyceryl caprylate'caprate; PEG-32 glyceryl laurate; PEG-6 glyceryl mono oleate; PEG-6 glyceryl linoleate; a propylene glycol mono fatty acid ester; a propylene

glycol di-fatty acid ester; propylene glycol laurate; propylene glycol caprylate/caprate; diethylene glycol monoethyl ether; transcutol; a monoglyceride; an acetylated monoglyceride; glycerol monooleate; glycerol monostearate; a mono-acetylated monoglyceride; a di-acetylated monoglyceride; monoacetin; diacetin; an anionic surfactant; a fatty acid salt; a bile salt; potassium laurate; triethanolamine stearate; sodium lauryl sulfate; an alkyl polyoxyethylene sulfate; sodium alginate; dioctyl sodium sulfosuccinate; sodium carboxymethylcellulose; calcium carboxymethylcellulose; a cationic surfactant; a pharmaceutically acceptable quaternary ammonium compound; benzalkonium chloride; cetyltrimethylammonium bromide; lauryldimethylbenzylammonium chloride; ~~polyethylene glycol;~~ PEG 1000; PEG 1500; and PEG 3400.

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Claim 46. (previously presented): The composition of claim 45, wherein the phospholipid is selected from the group consisting of a saturated phospholipid, an unsaturated phospholipid, a synthetic phospholipid, a natural phospholipid, and a combination thereof.

Claim 47. (currently amended): The composition of claim 39, wherein at least one hydrophilic component is selected from the group consisting of a low-molecular weight monohydric alcohol; a low-molecular weight polyhydric alcohol; ~~ethanol; a glycol; glycerol;~~ and a mixture thereof.

Claim 48. (previously presented): The composition of claim 39, in a dosage form for peroral, parenteral, transdermal, inhalation, or ophthalmic administration of said biologically active substance.

Claim 49. (previously presented): A process for preparing a dosage form of itraconazole comprising adding to a fluid aqueous medium a composition comprising stable solid particles of itraconazole having a volume weighted mean particle size in the range of 0.01 to 10 micrometers, which particles are dispersed in a non-aqueous carrier system comprised of:

a non-aqueous hydrophobic liquid in which said itraconazole is not soluble or is poorly soluble, and is present in an amount such that the itraconazole remains insoluble in the non-aqueous hydrophobic liquid;

D1 a surfactant system consisting of at least one surfactant which is soluble in said non-aqueous hydrophobic liquid, wherein at least a portion of which surfactant system absorbs to the surface of said particles; and a quantity of not more than about 10% of the total weight of said composition of one or more hydrophilic substances that provides a self-dispersing property to said composition, wherein upon addition of said composition to a fluid aqueous medium, said composition self-disperses in said fluid aqueous medium to form a suspension comprising droplets of non aqueous hydrophobic liquid containing particles of surface stabilized itraconazole suspended in the oily droplets of the dispersion and particles of said itraconazole migrated into said fluid aqueous medium wherein said particles have a size in the range of 0.01 to 10 micrometers and have associated therewith on the surface at least a portion of said surfactant system.

Claim 50. (previously presented): The process of claim 49, wherein the non-aqueous hydrophobic liquid is selected such itraconazole has a solubility of less than 25 mg/mL of the non-aqueous hydrophobic liquid.

Claim 51. (previously presented): The process of claim 50, wherein the non-aqueous hydrophobic liquid is selected such itraconazole has a solubility of from 0.02 to 16.0 mg/mL of the non-aqueous hydrophobic liquid.

Claim 52. (currently amended): The process of claim 40, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyl oleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, ~~ethyl alcohol,~~ corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, PEG-200, PEG-300, PEG-400, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

Claim 53. (previously presented): The process of claim 52, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, MIGLYOL 840, soybean oil, MIGLYOL 810, capric triglyceride, corn oil PEG-6 ester, propyleneglycol laurate, ethyl caprylate, MIGLYOL 818, apricot kernel oil, linoleic acid, triethyl citrate, MIGLYOL 812, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.

Claim 54. (previously presented): The process of claim 53, wherein the non-aqueous hydrophobic liquid is selected from the group consisting of decyloleate, ethyl oleate, ethyl myristate, isopropyl myristate, ethyl caprate, soybean oil, capric triglyceride, corn oil PEG-6

ester, propyleneglycol laurate, ethyl capl~ late, apricot kernel oil, linoleic acid, triethyl citrate, glycerol triacetate, glycerol a,a'-diacetate, 1,2-propanediol, glyceryl linoleate, and Plurol oleique CC 497.